

Serial No.: 10/026,819
Atty. Docket No.: P67397US0

REMARKS

The Office Action mailed March 15, 2006, has been carefully reviewed and by this Amendment, Applicants have amended claims 1, 2, 3, 5-15, 18, 24, 25, 29, 30, 33-40 and 42-60, and added claims 80-83. Claims 1-27, 29-73 and 80-83 are pending in the application. Claims 1, 60 and 82 are independent. Claims 61, 65, 66 and 73 have been withdrawn from further consideration.

The Examiner objected to the drawings as not showing every feature of the invention specified in the claims. With this Amendment, Applicants have submitted a replacement sheet with Figures 1a-1d in which the catheter outlet is identified with reference numeral "22". The specification has also been amended to correspond with the replacement sheet. No new matter has been added. Entry thereof is requested.

The Examiner rejected claims 1, 3, 4, 7, 16-20, 29, 33, 34, 60, 69, 71 and 72 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,041,085 to Osborne et al. ("Osborne"). Under 35 U.S.C. 103(a), the Examiner rejected claims 21-23, 26, 27, 41, 62-64, 67 and 68 as being unpatentable over Osborne in view of U.S. Patent No. 6,004,305 to Hursman et al., and rejected claims 32 and 70 as being unpatentable over Osborne in view of U.S. Patent No. 5,167,646 to Swafford.

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As clarified in amended claims 1 and 60, as well as new claim 82, the present invention is directed to a catheter assembly that includes a urinary catheter having a proximal end adapted for insertion into a urinary canal and an opposite distal end, and a *closed* catheter package having a generally tubular body with a cavity for accommodation of the catheter. The proximal end of the package has a catheter outlet through which the proximal end of the catheter may be "dismantled" or projected upon opening of the package. This amendment of claim 1 to clarify that the catheter package is closed until the proximal end of the catheter is projected through the catheter outlet is not shown in the prior art and is supported in the specification on page 6, lines 18-23; page 9, lines 4-10; page 10, lines 7-12 and 17-25; and page 12, lines 7-10 (see, in particular, the "liquid tight wetting pocket" on page 10, lines 8-9).

The closed catheter package of claim 1 is also provided, at an opposite distal end thereof, with a separate opening. Before the package is opened, this separate opening is closed by a closing structure that is connected to the catheter. The closing structure is configured to open the opening when the proximal end of the catheter is "dismantled" or projected from the package. This also is not shown or suggested by the prior art.

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Osborne teaches a catheter provided with a sleeve for moving the catheter from an unlocked or fully extended position, in which the catheter is inserted into the bladder, to a locked position in which the inserted end of the catheter (referred to by Osborne as the distal end) is drawn into a pigtail configuration that serves to retain the catheter within the bladder. There is no package nor any relationship between a package and a catheter, as claimed by the present invention.

More particularly, the elongated member tube 104 of Osborne is a drainage tube for draining fluids from the body of the patient. Accordingly, this tube is not a closed tube but instead includes an opening 109 and draw ports 122, 123 on the distal end thereof in communication with a passageway 107 that extends through the length of the tube. The proximal end of the tube 104 is connected to a locking collar 114 fitted within the sleeve 110 which serves to draw the catheter into the pigtail configuration once it has been inserted. However, the proximal end of the sleeve 110 is fitted with a standard Luer lock connector 124 having an open passageway therethrough such that fluid can flow from the opening 109 through the connector 124 to a fluid collection system (see column 3, lines 12-14).

Clearly, in Osborne there is no package that is opened by projection of the proximal end of the catheter through a

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catheter outlet. The "sealing" that occurs in Osborne between the locking collar 114 and the inner surface of the sleeve via flared end 106 and beveled surface 118 serves only to prevent fluid flow between the outside of the collar and the inside of the sleeve. This "sealing" does not result in a catheter package as claimed in claims 1, 60 and 82 because the sleeve of Osborne is not a *package* within which the catheter is accommodated and from which the proximal end of the catheter is projected upon package opening, but instead is only sleeve, overlying a part of the catheter remote from the insertion end, that is always "open" to fluid flow between 109 and 124 through the passageway 107.

Nor is there anything in Osborne to suggest that the connector 124, when received within the flared end 106, in any way closes an opening or seals tightly therewith. Nothing in Osborne suggests that the proximal end 112 of the sleeve is "closed" when the connector is received by the flared end 106 or that movement of the sleeve 110 toward the locked position in which the flared end 106 is remote from the connector 124 "opens" any assertedly closed opening. Rather, fluid is intended to flow through the passageway 107, through the center of the locking collar 114 and through the connector 124. It is this intended flow and the fact that the sleeve is always open via passageway 107 that necessitates the "sealing" of the flared end 106 against

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the inner surface of the sleeve so that the fluid cannot flow backwardly toward the distal end 111 of the sleeve but rather only forwardly through the connector 124 to the fluid collection system. The sleeve is only a mechanism for effecting the movement of the inserted end of the catheter from the extended position to the pigtail configuration while allowing effective fluid flow through the catheter in either position.

For at least the foregoing reasons, claims 1, 60 and 82 are patentable over the prior art. Favorable reconsideration and allowance thereof is requested. Claims 2-59, 61-73, 80, 81 and 83 are also in condition for allowance as claims properly dependent on an allowable base claim and for the subject matter contained therein, including additional species that incorporate all the limitations of the allowable generic claims 1 and 60.

The Examiner provisionally rejected claims 1, 3, 4, 7, 16, 21-23, 26, 27, 29, 32-34, 41, 60, 62-64, 67, 68 and 70-72 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of co-pending patent application, Serial No. 10/482,229, and claims 73-75 and 78-88 of co-pending patent application, Serial No. 10/183,984. Both of these co-pending applications being to Tanghoj et al. ("the Tanghoj applications"). In that the rejection is provisional, the conflicting claims in the Tanghoj applications not having

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been patented, Applicants request deferral of the resolution of this provisional rejection pending the identification of allowable subject matter.

With the foregoing amendments and remarks, the present application is in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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IN THE DRAWINGS:

Applicants have provided herewith a replacement drawing sheet setting forth Figures 1a-1d. Each of Figures 1c and 1d has been amended to add reference numeral 22 with associated lead line to the catheter outlet shown therein. No new matter has been added. Entry of the replacement drawing sheet is requested.